

# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/719,913	11/21/2003	Gary A. Dahl	EPICEN-09580 3340		
David A. Casin	7590 01/25/2007 nir	EXAMINER STAPLES, MARK			
	ARROLL, LLP				
Suite 350		ART UNIT PAPER NUMBE			
101 Howard St San Francisco,		1637			
				<u></u>	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS 01/25/2007			DADED		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

•		Applicatio	n No.	Applicant(s)				
Office Action Summary		10/719,91	3	DAHL ET AL.				
		Examiner		Art Unit				
		Mark Stapl	es	1637	•			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
WHIC - Exter after: - If NO - Failui Any r	ORTENED STATUTORY PERIOD FOR R HEVER IS LONGER, FROM THE MAILIN sions of time may be available under the provisions of 37 C SIX (6) MONTHS from the mailing date of this communicatio period for reply is specified above, the maximum statutory p te to reply within the set or extended period for reply will, by eply received by the Office later than three months after the d patent term adjustment. See 37 CFR 1.704(b).	IG DATE OF TH FR 1.136(a). In no eve on. period will apply and will statute, cause the appli	IS COMMUNICATION  nt, however, may a reply be tim  l expire SIX (6) MONTHS from to  cation to become ABANDONED	ely filed the mailing date of this (35 U.S.C. § 133).				
Status								
2a)□	<ol> <li>Responsive to communication(s) filed on 11/13/2006.</li> <li>This action is FINAL. 2b)  This action is non-final.</li> <li>Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.</li> </ol>							
Disposition of Claims								
5)□ 6)⊠ 7)⊠	<ul> <li>4)  Claim(s) 7-40 is/are pending in the application.</li> <li>4a) Of the above claim(s) 8, 9, 11-15, 31-35, and 39 is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 7,10,16-30,36-38 and 40 is/are rejected.</li> <li>7)  Claim(s) 27 and 37 is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>							
Applicati	on Papers	•						
10)⊠	The specification is objected to by the Exact The drawing(s) filed on <a href="1.1/21/2003">1.1/21/2003</a> is/are: Applicant may not request that any objection to Replacement drawing sheet(s) including the country of the oath or declaration is objected to by the	a) accepted o the drawing(s) borrection is require	e held in abeyance. See ed if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 C				
Priority u	inder 35 U.S.C. § 119							
12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) ☐ All b) ☐ Some * c) ☐ None of:  1. ☐ Certified copies of the priority documents have been received.  2. ☐ Certified copies of the priority documents have been received in Application No  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.								
2) Notic 3) Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-94 nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date <u>08/29/2006 &amp; 11/13/2006</u> .	8)	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	ite				

Art Unit: 1637

#### **DETAILED ACTION**

#### Election/Restrictions

- 1. Applicant's election without traverse of claims 1-2 and 4-6 of Group I (methods for making and amplifying transcription products) in the reply filed on November 13, 2006 is acknowledged. Further acknowledgement is made of cancellation of claims 1-6 and submission of new claims 7-40.
- 2. Newly submitted claims 8, 9, 11-15, 31-35, and 39 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons. The following were not originally presented in elected Group I and constitute independent and distinct inventions:

New Group III is of base claims 31 and 32 and dependent claims 33-35 is drawn to new independent and distinct methods of linearizing to obtain transcription products. Group III is classified in class 435, subclass 91.2.

Inventions III and originally presented Inventions I and II are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed, Groups III has a

Art Unit: 1637

materially different design and mode of operation of linearizing to produce a transcription product. Groups III does not overlap in scope with originally presented Groups I and II as these are drawn to production of transcription products with circular templates and thus Group III is not an obvious variant of originally presented Groups I and II. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Within new Group III are also the subcombination of dependent claims 8 and 9 and dependent claims 11, 12, 14, and 15 which recite the new independent and distinct methods of linearizing to obtain a transcription product. Group III further encompasses the subcombination claim 39, drawn to new independent and distinct methods of linearizing to obtain a transcription product. These Group III claims are a subcombination of elected Group I claims.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the

Art Unit: 1637

particulars of the subcombination as claimed because Applicant has originally presented Group I without the particulars of the subcombination in the original claim presentation filed on 11/21/2003. Thus, Applicant admits that Group I does not require the particulars of the subcombination. The subcombination has separate utility, such as linearizing circular oligonucleotides from the process of rolling circle amplification (RCA).

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Within non-elected Group II is claim 13, which recites an analyte-binding substance (ABS), a subcombination of Group I.

Art Unit: 1637

Inventions I and this Invention II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Applicant has originally presented Group I without the particulars of the Group II subcombination, in the original claim presentation filed on 11/21/2003. Applicant originally presented Group I and Group II in independent and distinct claim sets without any subcombination. Thus, Applicant admits that Group I does not require the particulars of the subcombination. The subcombination has separate utility, such as capturing labeled oligonucleotide fragments produced in a standard amplification reaction, such as PCR.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Art Unit: 1637

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 8, 9, 11-15, 31-35, and 39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

In summary, new claims 7, 10, 16-30, 36-38, and 40 as filed on 11/13/2006 will be fully examined for patentability.

# Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Application/Control Number: 10/719,913 Page 7

Art Unit: 1637

## **Drawings**

4. The drawings are objected to because Figure is misspelled as "Figur" in several of the drawings and numerous omissions of usually single letters in the text of the Figures. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

# Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should reflect what

Art Unit: 1637

is recited in the elected claims, a "double-stranded promoter" which is found in the present title is not recited in the elected claims.

- 6. The abstract of the disclosure is objected to because the abstract should be amended to the elected claims; the elected claims do not recite compositions or kits. Correction is required. See MPEP § 608.01(b).
- 7. The use of the trademarks MASTERPURE™, ISOTHERM™, BCABEST™, REPLIPHI™, SIGNALPROBE™, and SEQUITHERM™ have been noted in this application. They and any other trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

## Sequence Rules Compliance

Pages 4 and 33 respectively contain sequences without SEQ ID NOs. If these sequences are included in the sequence listing provide by Applicant, the specification should be amended to include the SEQ ID NOs. If these sequences were not included in the sequence listing filed 05/20/2004, Applicant should provide a substitute sequence listing and a CRF that include those sequences.

Art Unit: 1637

# Claim Objections

8. Claims 27 and 37 are objected to because of the following informalities: omission of the "' to describe the "5' end". Appropriate correction is required.

## Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28, 30, and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the process by which the RNA annealed to the first-strand cDNA is accomplished.

Claim 30 recites the limitation "said target nucleic acid" in 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 30 recites the limitation "cDNA" in steps 4 and 5. There is insufficient antecedent basis for this limitation in the claim. By definition, cDNA is derived from mRNA. There is no antecedent basis for mRNA and hence there is no antecedent basis for cDNA. It is noted that steps 1-3 of claim 30 recite "target nucleic acid" which encompasses DNA, RNA, and all subtypes of DNA and RNA.

Art Unit: 1637

It is further noted that the art defines cDNA as follows:

"By definition, cDNA is double-stranded DNA that was derived from mRNA . . . "

Campbell, M. A. <u>cDNA Production</u>. 3<sup>rd</sup> paragraph. © Copyright 2002 Department of Biology, Davidson College, Davidson, NC 28036. retrieved 17 Jan. 2007.

<a href="http://www.bio.davidson.edu/COURSES/genomics/method/cDNAproduction.html">http://www.bio.davidson.edu/COURSES/genomics/method/cDNAproduction.html</a>

Due to the claims rejection noted above, the following claim interpretations have been made on other claims in order to determine whether prior art is applicable.

# Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 10, 16-24, 26, 28, 30, 36, 38, and 40 are rejected under 35
U.S.C. 102(b) as being anticipated by Lorincz et al. (US Patent No. 6,136,535, issued Feb. 2000).

Regarding claims 7, 10, 16-22, 24, 28, 30, 36, 38, and 40, Lorincz et al. (Feb. 2000) teach a method comprising the steps of:

Art Unit: 1637

- (1) obtaining said target nucleic acid (see Figure 1A and see claim 1 or 7 where the target nucleic acids may be a sample; see column 17 lines 14-16: "This process is capable of analyzing multiple samples sequentially or simultaneously"; and see column 3 lines 15 and 16: "Any nucleic acid may be amplified by the method of the present invention");
- (2) obtaining said sense promoter primer, the sense promoter primer comprising a 5'end portion comprising a sense transcription promoter and a 3'-end portion that
  is complementary to the target (see Figure 1A and see claim 1 or 7);
- (3) annealing [hybridizing] the sense promoter primer with the target nucleic acid so as to form a target nucleic acid-sense promoter primer complex (see Figure 1A and see claim 1 or 7);
- (4) contacting the target nucleic acid-sense promoter primer complex with a polymerase under polymerization reaction conditions to obtain first-strand nucleic acid that is complementary to the target sequence (see Figure 1A and see claims 1 and 6, or 7 and 11);
- (5) ligating the first-strand nucleic acid to itself under ligation conditions so as to obtain circular sense promoter-containing first-strand nucleic acid (see column 4 lines 3 and 4: "Optionally, a ligation reaction may be carried out to fill the gap between the promoter and the template");
- (6) obtaining an anti-sense promoter oligonucleotide (see Figure 4 and the circle T7 oligo given there and note that this anti sense promoter is attached to and antibody which an analyte binding substance, ABS);

Art Unit: 1637

(7) annealing the anti-sense promoter oligonucleotide to the circular sense promoter-containing first-strand nucleic to obtain a circular transcription substrate (see Figure 4); and

(8) contacting the circular transcription substrate with an RNA polymerase under transcription conditions wherein a transcription product is obtained (see Figure 4 for amplification of the circular substrate with polymerase to obtain additional product. And for use of an RNA polymerase see column 3 lines 54-57: "This product is subjected to transcription using, for example, RNA polymerase. In this way, a template DNA [transcription substrate] can be indirectly amplified without the need to carry out any cycled reaction").

Regarding claims 16 and 17, Lorincz et al. (Feb. 2000) teach a method using a wild type T7 RNA polymerase (see column 11, lines 23-25).

Regarding claim 18, Lorincz et al. (Feb. 2000) teach a method using four dNTPs (dATP, dGTP, dCTP, dTTP) four NTPs (ATP, GTP, CTP, UTP), see column 23, lines 17-20.

Regarding claim 19, Lorincz et al. (Feb. 2000) teach an *in vitro* method (see column 2 lines 61-64).

Regarding claim 22, Lorincz et al. (Feb. 2000) teach a method using messenger RNA, mRNA (see column 5 lines 7).

Regarding claims 23 and 40, Lorincz et al. (Feb. 2000) teach a synthetic promoter (see Example 1 for synthetic promoter-primer).

Art Unit: 1637

Regarding claim 24, Lorincz et al. (Feb. 2000) teach a target specific sequence (see claim 1).

Regarding claim 26 and 30, Lorincz et al. (Feb. 2000) teach a method for amplifying the amount of a template-complementary product, the method comprising the steps of:

- (1) obtaining a transcription product (see Figure 1A and see claim 1 or 7; see column 3 lines 15 and 16: "Any nucleic acid may be amplified by the method of the present invention"; and see column 6 lines 23 and 24: "generating multiple RNA transcripts", nucleic acids, which are transcription products);
- (2) obtaining a sense promoter primer comprising a 3'-end portion that is complementary to the 3'-end of the transcription product (see Figure 1A and see claim 1 or 7; );
- (3) annealing [hybridizing] the sense promoter primer to the transcription product (see Figure 1A and see claim 1 or 7);
- (4) primer-extending the sense promoter primer annealed to the transcription product acid with a DNA polymerase under DNA synthesis conditions to obtain first-strand cDNA (see Figure 1A and see claims 1 and 6, or 7 and 11; see column 3 lines 15 and 16: "Any nucleic acid may be amplified by the method of the present invention"; and see column 13 line 30-32: "Transcripts may also be subjected to a reverse transcriptase reaction in order to generate cDNAs . . . ");

Art Unit: 1637

(5) ligating the first-strand cDNA, wherein the 5'-end is covalently joined to the 3'-end of the first-strand cDNA to obtain circular sense promoter-containing first-strand DNA (see column 4 lines 3 and 4: "Optionally, a ligation reaction may be carried out to fill the gap between the promoter and the template");

- (6) annealing an anti-sense promoter oligonucleotide to the circular sense promoter-containing first-strand cDNA to obtain a circular substrate for transcription (see Figure 4 for circle T7 oligo); and
- (7) contacting the circular substrate for amplification with a RNA polymerase under conditions to obtain additional transcription product (see Figure 4 for amplification of the circular substrate with polymerase to obtain additional product).

Regarding claims 28 and 38, Lorincz et al. (Feb. 2000) teach a wash step that removes the RNA hybrid (annealed RNA) from other components (see Example 2, especially line 38).

Regarding claims 36, Lorincz et al. (Feb. 2000) teach a method for amplifying an amount of template-complementary transcription product, the method comprising:

(1) obtaining a transcription product by transcription of a template of a probe that is complexed with an analyte binding substance-oligo (see Figure 4 and claims 7, 10, 13, and 16; see column 3 lines 15 and 16: "Any nucleic acid may be amplified by the

Art Unit: 1637

method of the present invention"; and see column 6 lines 23 and 24: "generating multiple RNA transcripts", nucleic acids, which are transcription products);

- (2) obtaining a sense promoter primer comprising a 3'-end portion that is complementary to the 3'-end of the transcription product (see Figure 4 and claims 7 10, 13, and 16);
- (3) annealing the sense promoter primer to the transcription product;
- (4) primer-extending the promoter primer annealed to the transcription product with an RNA-dependent DNA polymerase under DNA synthesis conditions so as to obtain first-strand cDNA (see column 13 lines 9-11: "Transcripts may also be subjected to a reverse transcriptase reaction in order to generate cDNAs which may be analyzed");
- (5) ligating the first-strand cDNA, wherein the 5'-end is covalently joined to the 3'-end of the first-strand cDNA so as to obtain circular sense promoter-containing first-strand cDNA (see column 4 lines 3 and 4: "Optionally, a ligation reaction may be carried out to fill the gap between the promoter and the template");
- (6) annealing an anti-sense promoter oligo to the circular sense promoter-containing first-strand cDNA so as to obtain a circular substrate for transcription (see Figure 4 and the circle T7 oligo given there);
- (7) contacting the circular substrate for transcription with an RNA polymerase under transcription conditions so as to obtain additional transcription product; and
- (8) obtaining the additional transcription product (for claims 7 and 8 see Figure 4 for amplification of the circular substrate with polymerase to obtain additional product. And

Art Unit: 1637

for use of an RNA polymerase see column 3 lines 54-57: "This product is subjected to transcription using, for example, RNA polymerase. In this way, a template DNA [transcription substrate] can be indirectly amplified without the need to carry out any cycled reaction").

#### Claim Rejections - 35 USC § 103

- 11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1637

Claims 25, 27, 29, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorincz et al. (Feb. 2000) as applied to claims 26 and 36 above, and further in view of Hall et al. (US Patent No. 5,994,069, issued 1999).

Lorincz et al. (Feb. 2000) teach as noted above and teach a 3' end labeled phosphate labeled promoter primer, which is a synthetic primer promoter.

Lorincz et al. (Feb. 2000) do not specifically teach a promoter primer comprising a phosphate group on its 5' end.

Hall et al. (1999) teach labeling the 5' end (see claims 9 and 12).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Lorincz et al. by labeling, instead of the 3'end, the 5' end of a oligonucleotide promoter primer with a phosphate group as suggested by Hall et al. with a reasonable expectation of success. The motivation to do so is provided by Hall et al. who teach the successful detection of olignucleotides which are labeled on the 5' end. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

## **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

Art Unit: 1637

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 26-30 and 36-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 67-92, 94-98, 100-104, 106, and 107 of copending Application No. 10/744,815. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application contain the critical elements of the claims of the instant application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Given the large number of related cases, Applicant is requested to comply with 37 CFR 1.56 by identification of related copending applications and providing a copy of the current version of claims pending in the those applications that are particularly close to issuance, which raise double patenting issues.

Art Unit: 1637

#### Conclusion

13. Claims 7, 10, 16-30, 36-38, and 40 are not free of the prior art.

14. Claims 8, 9, 11-15, 31-35, and 39 are withdrawn from consideration.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 7:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples Examiner Art Unit 1637 January 16, 2006

GARY BENZION, PH.D SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600